UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,143	12/31/2003	Maurice Behague	069208.0115	7930

23640 7590 03/27/2008

BAKER BOTTS, LLP
910 LOUISIANA
HOUSTON, TX 77002-4995

EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
03/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

debbie.allen@bakerbotts.com

Office Action Summary	Application No.	Applicant(s)	
	10/750,143	BEHAGUE ET AL.	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2007 has been entered.

Response to Arguments

2. Applicant's arguments filed December 20, 2007 have been fully considered but they are not persuasive. With respect to arguments regarding the rejection of claims 1-3 and 5 under 35 U.S.C. 102 as anticipated by O'Riordan: Applicant argues that O'Riordan does not disclose collecting a biological fluid by natural flow, without a pump. To support the argument, applicant states that O'Riordan pumps blood bleeding from surgical cavities, not from veins, and thus one of ordinary skill in the art would not use the device of O'Riordan to collect biological fluid by natural flow and in fact blood from a surgical cavity would not flow into the collection device. This is not persuasive because blood from a surgical cavity is certainly capable of flowing on its own. Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the biological fluid flows from a particular site or vessel such as a vein) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Second, applicant is referred to page 3, lines 45-47, where

O'Riordan explicitly discloses that the instant device can be used in extracorporeal blood circuits and other blood collection devices wherein the suction wand 10 is replaced with a blood-collecting needle for receiving blood from the arterio-venous system of a patient. This embodiment necessarily discloses the step of collection of a bodily fluid, in this case blood, by natural flow through the collection needle. Thus the prior art of O'Riordan still anticipates claim 1

Applicant further argues that the rejection of claims 1-3 and 5 under 35 U.S.C. 102 is improper as it is based upon teachings not found in O'Riordan. This is not persuasive as applicant has not referred to any explicit teachings of O'Riordan which examiner has cited but which applicant cannot find. Additionally, examiner has addressed all of the perceived deficiencies of O'Riordan as outlined by applicant, and thus the rejection is proper because all limitations of claims 1-3 and 5 are explicitly taught by O'Riordan.

As to applicant's arguments that O'Riordan does not teach the step "wherein the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and/or preservation solution", O'Riordan teaches this step in detail on Page 4, lines 15-48. Specifically, O'Riordan discloses in summary in lines 47-48 that "with the above-described system, anticoagulant can be automatically delivered as a function of either volume of blood salvaged or the salvage rate" (i.e the volume of blood collected or blood collection fluid flow rate) O'Riordan further discloses on Page 5, lines 19-23 another embodiment of the sensor system for use with this system in which the instant array of optical detectors used to determine flow rate of blood is replaced by a flow detector in tubing segment 22 leading into reservoir 22 to monitor rate of flow in to the reservoir of either blood or anticoagulant. The monitored rate of flow from the flow detector is used with a clock for detecting time interval of flow of either blood or anticoagulant, and this arrangement is used to determine the flow of anticoagulant to be infused into the reservoir in accordance with

the system disclosed by O'Riordan on page 3, lines 15-47. Hence O'Riordan also meets this limitation of claim 1.

Applicants' arguments with regard to dependent claim 4 as rejected under 35 U.S.C. 103 as unpatentable over O'Riordan have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claim 1, which have been addressed *supra*.

With respect to arguments regarding the provisional double patenting rejection of claims 1-5: Applicant argues that the claims of the copending application (specifically, independent claim 15) recite the step of collecting measuring a volume of fluid collected whereas the instant claims recite the step of measuring fluid flow rate and thus claim 15 of the copending application 11/196,706 is not an obvious variant of claim 1 of the instant application. This is not persuasive because the step of measuring fluid flow rate as recited in claim 1 of the instant application necessarily involves the steps of measuring volume of biological fluid collected (as recited in claim 15 of the copending application) and measuring time elapsed from the beginning of flow of fluid into the claimed reservoir until the time at which flow of fluid into the reservoir ceases. The method of the copending application is perfectly capable of including the step of measuring time elapsed during flow of fluid into the reservoir, because one of ordinary skill in the art can easily look at a watch or clock to determine time elapsed. Thus claim 15 is an obvious variation of claim 1 of the instant application and the double patenting rejection of claims 1-5 is maintained herein.

Oath/Declaration

3. The declaration filed December 19, 2007 has been reviewed and is accepted. The objection to the oath has been withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan et al (EP 583,148 A2).

With respect to **claim 1:** O'Riordan teaches a method of collecting a biological fluid comprising: collecting a biological fluid by natural flow via a needle (Page 3, lines 45-47) and without a pump, since the suction wand of the alternate embodiment of blood collecting means taught by O'Riordan is not used. The instant method also comprises the steps of measuring a fluid flow rate of the biological fluid via flow detector 22 (Page 5, lines 19-21), and pumping anticoagulant and/or preservation solution to the collected biological fluid at a solution flow rate. (Page 3, lines 54,55) The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 3, lines 54, 55; Page 4, lines 15-48, Page 5, lines 19-23) Specifically, O'Riordan discloses in lines 47-48 that "with the above-described system, anticoagulant can be automatically delivered as a function of either volume of blood salvaged or the salvage rate" (i.e the volume of blood collected or blood collection fluid flow rate). O'Riordan further discloses another embodiment of the sensor system on Page 5, lines 19-23, for use with this system. In this embodiment, the instant array of optical detectors 32 described on page 4 used to determine flow rate of blood is replaced by a flow detector in tubing segment 22 leading into reservoir 16 to monitor rate of flow in to the reservoir of either blood or anticoagulant. The monitored rate of flow from the flow detector is used with a clock for

detecting time interval of flow of either blood or anticoagulant, and this arrangement is used to determine the flow of anticoagulant to be infused into the reservoir in accordance with the system disclosed by O'Riordan on page 3, lines 15-47.

With respect to **claim 2:** The method taught by O'Riordan further comprises the steps of collecting the biological fluid in a collection bag 16 (Fig. 4, Page 4, lines 53-55) and pumping the anticoagulant and/or preservation solution to the collection bag 16 (Page 4, lines 53-55). The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate Qb to preserve a selected ratio in the collection bag 16 between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 4, lines 15-33)

With respect to **claim 3:** The biological fluid taught by O'Riordan comprises blood. (Abstract)

With respect to **claim 5:** The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein the act of pumping comprises pumping using a peristaltic pump 42 having a variable rotation speed, inasmuch as the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant. (Page 3, lines 54, 55; Page 5, lines 4,5) The method also comprises adjusting the variable rotation speed to obtain the appropriate solution flow rate. (Page 3, lines 54,55; Page 5, lines 4,5)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan et al ('148).

With respect to **claim 4:** The method taught by O'Riordan comprises a step of measuring a fluid flow rate Qb, wherein measuring a fluid flow rate of the biological fluid comprises calculating the variation in volume of the fluid collected, wherein such volume has an associated weight directly correlated to said volume by the density of the biological fluid. O'Riordan does not teach that measuring a fluid flow rate of the biological fluid comprises calculating the variation in weight of the fluid collected. However, the data accumulated by performing the step of measuring the variation in volume can easily be used by one of ordinary skill in the art to calculate variation in weight by multiplying the variations in volume by the density of the fluid (know because the fluid is blood) and multiplying the resulting mass variation by the gravitational constant to produce the associated weight variations. Therefore, it would be obvious to one of ordinary skill in the art to modify the method taught by O'Riordan such that the step of measuring fluid flow rate Qb further comprises the step of calculating the variation in weight of fluid collected with a reasonable expectation of success to monitor the amount of fluid collected to determine when a sufficient amount of blood has been collected and the process can be stopped.

Double Patenting

6. The provisional nonstatutory double patenting rejection made in the previous Office action mailed May 7, 2007 is maintained herein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761